

UNITED STATES EPARTMENT OF COMMERCE United States Patent and Trademark Offic

Address: COMMISSIONER OF PATENTS AND TRADEMARKS Washington, D.C. 20231

	APPLICATION NO. FILING DATE		FIRST NA	FIRST NAMED INVENTOR		ATTORNEY DOCKET NO.	
	09/529,	319 02/0	9/00 POULIN		R	ILEX:040/019	
Γ			НМ22/0628		EXAMINER		
	STEVEN	L HIGHLAND		2/0020	KUMAR.S		
	FULBRIG	HT & JAWOR			ART UNIT	PAPER NUMBER	
	SUITE 2400 600 CONGRESS AVENUE AUSTIN TX 78701		JE		1621	9	
	HUDIIN	17 /0/01			DATE MAILED:	06/28/01	

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Application No. 09/529,319

Applicant(s)

Poulin et al

Office Action Summary

Examiner

Art Unit Shailendra Kumar

1621 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on Feb 9, 2000 2b) X This action is non-final. 2a) \square This action is **FINAL**. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213. Disposition of Claims is/are pending in the application. 4) X Claim(s) 1-43 4a) Of the above, claim(s) ______ is/are withdrawn from consideration. is/are allowed. 5) Claim(s) 6) Claim(s) 1-43 is/are rejected. is/are objected to. 7) Claim(s) ______ are subject to restriction and/or election requirement. 8) Claims Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on Feb 9, 2000 is/are objected to by the Examiner. 11) ☐ The proposed drawing correction filed on _______ is: a) ☐ approved b) ☐ disapproved. 12) ☐ The oath or declaration is objected to by the Examiner. Priority under 35 U.S.C. § 119 13) Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d). a) \square All b) \square Some* c) \square None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. 🗔 Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). *See the attached detailed Office action for a list of the certified copies not received. 14) Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e). Attachment(s) 18) Interview Summary (PTO-413) Paper No(s). 15) Notice of References Cited (PTO-892) 16) X Notice of Draftsperson's Patent Drawing Review (PTO-948) 19) Notice of Informal Patent Application (PTO-152) 17) Information Disclosure Statement(s) (PTO-1449) Paper No(s). 20) Other:

Page 2

Application/Control Number: 09/529,319

Art Unit: 1621

DETAILED ACTION

Claims 1-43 are pending in this application.

1. Receipt-is-acknowledged-of-papers-submitted-under-35-U-S-C-1-19(a)-(d), which papers have been placed of record-in the file.

Claim Rejections - 35 U.S.C. § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims read as "wherein carbon atom of said original polyamine comprises an amide group, and the carbon is located between two internal nitrogen atoms", it is not clear as to which carbon atom is being referred to, because in an a polyamine there are various carbon atoms between various nitrogen atoms, and further, claim 3, reads "dimer of said original polyamine, the monomer of said dimer being linked together by a spacer side chain, anchored to the amido group of each monomer", again, the chemistry should be clear as to what is being claimed, the

Art Unit: 1621

description, is so unclear as to come to any conclusion of what is being claimed. Thus claims are rendered indefinite.

4. Claims 16-20 provides for the use of synthetic derivative, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 16-20 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPO 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPO 475 (D.D.C. 1966).

Claim Rejections - 35 U.S.C. § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 6. Claims 1-12, 15, 22-26, 28-43 are rejected under 35 U.S.C. 102(b) as being anticipated by Huber et al, J. Biol. Chem. 1996).

Art Unit: 1621

Huber et al, in the title reads on the same compound as claimed herein, thus anticipating the claims.

Claim Rejections - 35 U.S.C. § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
 - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 8. The factual inquiries set forth in *Graham* v. *John Deer Co.*, 383 U.S. 1, 148 USPO 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:
 - 1. Determining the scope and contents of the prior art.
 - 2. Ascertaining the differences between the prior art and the claims at issue.
 - 3. Resolving the level of ordinary skill in the pertinent art.
 - 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CAR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was

Art Unit: 1621

made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1-15 and 21-43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huber et al.

Huber et al teach structurally similar compounds as claimed herein. Note, the title of the reference.

It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to obtain compounds within the structure of the reference, because they are structurally so similar to those claimed herein, with the reasonable expectation of achieving a successful pharmaceutical composition, absent evidence to the contrary.

Double Patenting

10. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPO 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPO 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

11. Claims 13-15 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 13-15 of prior U.S. Patent No. 6,083,496. This is a double patenting rejection.

Application/Control Number: 09/529,319

Art Unit: 1621

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper tames extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPO 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPO 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPO 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPO 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CAR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CAR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CAR 3.73(b).

13. Claims 1-12, and 21-43 are rejected under the judicially created doctrine of double patenting over claims 1-16 of U. S. Patent No. 6,083,496 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: the generic structure of the instant claims extensively overlap those of the above patent, as evidenced by compounds of claims 13-15.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPO 210 (CCPA 1968). See also MEP. § 804.

No claim is allowed.

Art Unit: 1621

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to S.Kumar whose telephone number is (703) 308-4519. The examiner can normally be reached on Monday to Friday from 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Johann Richter, can be reached on (703) 308-4532. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

S.Kumar

6/28/01

SHAILENDRA KUMAR PRIMARY EXAMINER GROUP 1298)607